**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k053422

**B. Purpose for Submission:**

New device

**C. Measurand:**

Benzoylecgonine

**D. Type of Test:**

Qualitative, lateral flow immunoassay

**E. Applicant:**

American BioMedica Corporation

**F. Proprietary and Established Names:**

RapidOne Cocaine 150 Test

**G. Regulatory Information:**

1. Regulation section:

   21 CFR 862.3250

2. Classification:

   Class II

3. Product code:

   DIO

4. Panel:

   Toxicology, 91

## H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   RapidOne Cocaine 150 Test is a one-step lateral flow immunoassay for the qualitative detection of benzoylecgonine in human urine.

   RapidOne Cocaine 150 Test is intended for professional use. It is not intended for over the counter sales to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. The immunoassay is a simplified, qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas chromatography/mass spectrometry (GC/MS).

   RapidOne Cocaine 150 Test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result.

3. Special conditions for use statement(s):

   For professional use.

   RapidOne Cocaine 150 Test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result.

4. Special instrument requirements:

   Not applicable

## I. Device Description:

The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold antibody is dried at one end of the membrane. The test kit contains instructions for use, 50 test devices to which 2 absorbent pads are attached. The lower pad contains anti-benzoylecgonine monoclonal antibody complex. The test line, comprised of a BSA-drug conjugate for the specific analyte, is dried in a thin band on the membrane. A second band (control line) containing goat-anti-mouse IgG is placed above the test line. The uppermost absorbent pad acts as a reservoir to collect the urine sample after it migrates through the membrane.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   American BioMedica RapidOne –Cocaine Test

2. Predicate 510(k) number(s):

   k990822

3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| **Principle** | Lateral flow immunoassay | Same |
| **Label** | Colloidal gold | Same |
| **Intended use** | Detects cocaine and its metabolite | Same |

| Differences | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| **Cut-off** | 150 ng/mL | 300 ng/mL |

## K. Standard/Guidance Document Referenced (if applicable):

None referenced.

## L. Test Principle:

The assay is a one-step immunoassay in which a specially labeled drug (drug conjugate) competes with drug which may be present in the sample for the limited number of binding sites on an antibody.

## M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   *a. Precision/Reproducibility:*

   Reproducibility studies were performed using commercially available benzoylecgonine standards. Each sample at each concentration (0, 75, 113, 150 and 187 ng/mL) was tested 4 times, twice daily for 5 days. The results are presented in the following table:

| Concentration ng/mL | Number | Results | % Agreement |
|---|---|---|---|
| 0 | 40 | 40 negative | >99 |
| 75 | 40 | 7 positive | 83 |
| 113 | 40 | 33 positive | 83 |
| 150 | 40 | 40 positive | >99 |
| 187 | 40 | 40 positive | >99 |

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The sponsor conducted real time and accelerated studies. The protocols and acceptance criteria were described and found to be acceptable. The sponsor claimed the following expiration date: 1 year when stored at room temperature or 4 - 25˚C.

The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. *Detection limit:*

A drug-free urine pool was spiked with benzoylecgonine at the following concentrations: 25% and 50% below the cutoff, cutoff and 25% above the cutoff. The results are presented in the table below:

| Benzoylecgonine Concentration ng/mL | Percent of Cutoff | n | Negative Results | Positive Results |
|---|---|---|---|---|
| 0 | 0% | 10 | 10 | 0 |
| 75 | 50% | 10 | 8 | 2 |
| 113 | 75% | 10 | 2 | 8 |
| 150 | 100% | 10 | 0 | 10 |
| 187 | 125% | 10 | 0 | 10 |

e. *Analytical specificity:*

A study was conducted to determine the cross-reactivity of the test with compounds in drug-free negative urine. The following compounds showed no

interference at concentrations of 100 ug/mL when tested with the RapidOne Cocaine 150 Test:

Heroin (Diacetylmorphine)

11-Hydroxy-Δ9-Tetrahydrocannabinol

11-Nor-Δ8-Tetrahydrocannibinol-9-Carboxylic Acid

11-Nor-Δ9-Tetrahydrocannibinol-9-Carboxylic Acid

11-Nor-Δ9-THC-9-Carboxylic Acid Glucuronide

Cross-reactivity was established by spiking various concentrations of drug free urine with similarly structured drug compounds that produced a positive result. The data is presented in the table below:

| **Compound** | **Concentration ng/mL** |
|---|---|
| Benzoylecgonine | 150 |
| Cocaethylene | 150 |
| Cocaine | 100 |
| Metoclopramide | 80,000 |
| Procaine (Novacaine) | 75,000 |

pH: Drug free urine was adjusted to pH values from 3 – 11. Exogenous benzoylecgonine was added to these specimens to give a final concentration of 150 ng/mL. The spiked, pH-adjusted urine was tested with the RapidOne Cocaine 150 Test and interpreted according to the package insert instructions. The results demonstrate that varying ranges of pH did not interfere with the performance of the test and the ability of the device to detect 150 ng/mL of benzoylecgonine.

Specific Gravity: A drug free urine (specific gravity 1.020) was diluted to produce various lower specific gravity values. Exogenous benzoylecgonine was added to these specimens to give a final concentration of 150 ng/mL. In addition an aqueous solution (specific gravity 1.000) of 150 ng/mL of benzoylecgonine was evaluated. These specimens with a specific gravity values ranging from 1.000 – 1.020 were tested with the device and demonstrated that varying ranges of specific gravity did not interfere with the performance of the test.

*f. Assay cut-off:*

Studies demonstrating assay performance around the cutoff (150 ng/mL benzoylecgonine) are described in the precision section above. Currently, the Substance Abuse and Mental Health Services Administration (SAMHSA) recommends 300 ng/mL as the screening cutoff for cocaine positive specimens.

2. Comparison studies:

*a. Method comparison with predicate device:*

A method comparison evaluation was conducted using ninety-eight (98) clinical urine samples versus Gas Chromatography/Mass Spectrometry (GC/MS) at the 150 ng/mL cut-off. These comparisons of data yielded the following results:

RapidOne Cocaine 150 Test versus GC/MS at the 150 ng/mL cut-off:

| RapidOne Cocaine-150 Test | <-50% of cutoff | Between -50% and cutoff | Between cutoff and +50% | >+50% of cutoff | % Agreement with GC/MS |
|---|---|---|---|---|---|
| Positive | 1 | 7 | 22 | 10 | 80% |
| Negative | 58 | 0 | 0 | 0 | >99% |

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

## O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.